K071319

Bio-Rad Laboratories
i-STAT Activated Clotting Time (ACT) Control Set
Summary of Safety and Effectiveness

JUN 26 2007

1.0 **Submitter**

Bio-Rad Laboratories
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Irvine, California 92618-2017
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

May 7, 2007

2.0 **Device Identification**

Product Name:	i-STAT Activated Clotting Time (ACT) Control Set
Common Name:	Plasma, coagulation control Hematology and Pathology Devices
Classifications:	Class II
Product Code:	GGN
Regulation Number:	21 CFR 864.5425

3.0 **Device to Which Substantial Equivalence is Claimed**

i-STAT COAGULATION CONTROL SET
BIOPOOL INTL., INC.
6025 Nicolle St.
Ventura, CA 93003

510 (k) Number: K981752

4.0 **Description of Device**

This is a lyophilized product prepared from human plasma, with added purified biochemicals and preservatives. The control is provided in lyophilized form for increased stability.

5.0 **Intended Use**

i-STAT Activated Clotting Time (ACT) Control is used to verify the integrity of newly received i-STAT Activated Clotting Time cartridges.

6.0 Comparison of the new device with the Predicate Device

i-STAT Activated Clotting Time (ACT) Control Set claims substantial equivalence to the i-STAT Coagulation Control Set currently in commercial distribution (K981752).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Activated Clotting Time (ACT) Control Set (New Device)	BIOPOOL INTL., INC i-STAT Coagulation Control Set (Predicate Device K981752)
Similarities		
Intended Use	i-STAT Activated Clotting Time (ACT) Control Set is used to verify the integrity of newly received i-STAT Activated Clotting Time cartridges.	i-STAT Coagulation Control Set is intended for use to verify the integrity of newly newly received i-STAT ACT cartridges.
Matrix	Human plasma	Human plasma
Form	Lyophilized	Lyophilized
Storage (Unopened)	Refrigerated (2 to 8°C)	Refrigerated (2 to 10°C)
Open Vial stability	Use immediately	Use immediately

7.0 Statement of Supporting Data

Stability studies have been performed to determine shelf life for this control. Product claims are as follows:

- Shelf Life: 18 months at 2 to 8°C

All supporting data is retained on file at Bio-Rad Laboratories.

Indications for Use

510(k) Number (if known): K071319

DEVICE NAME: **i-STAT ACT CONTROL SET**

Indications For Use: i-STAT® Activated Clotting Time (ACT) Control is used to verify the integrity of newly received i-STAT® Activated Clotting Time cartridges.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 26 2007

Maria Zeballos
Regulatory Affairs Specialist
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k071319
Trade/Device Name: i-STAT Activated Clotting Time (ACT) Control Set
Regulation Number: 21 CFR 864.5425
Regulation Name: Plasma, coagulation control; Hematology and Pathology Devices
Regulatory Class: Class II
Product Code: GGN
Dated: June 4, 2007
Received: June 6, 2007

Dear Ms. Zeballos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071319

DEVICE NAME: **i-STAT ACT CONTROL SET**

Indications For Use: i-STAT® Activated Clotting Time (ACT) Control is used to verify the integrity of newly received i-STAT® Activated Clotting Time cartridges.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Evaluation and Safety

510(k) K071319